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10/089,454

01/05/2004

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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/089,454 | Applicant(s) RENARD ET AL. | |
| | Examiner Valarie Bertoglio | Art Unit 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on N/A is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application was filed January 5, 2004, is a 371 national stage filing of PCT/FR00/02698, filed September 29, 2000, which claims benefit to foreign application 99/12287 filed October 1, 1999 in France.

Applicant's reply filed 10/29/2008 has been received. Claims 1-12 and 25 are cancelled. Claim 13 and 16 are currently amended. Claims 13-24 are pending and under consideration in the instant office action.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-24 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claim 13 remains vague and unclear. Although the claim has been amended to add methodology required to obtain an embryo, step (ii) still recites that an embryo is obtained prior to activation of the oocyte. See page 3 of the office action dated 04/30/2008.

The aspect of the rejection of claim 13 as lacking antecedent basis for the limitation "said nucleus" is withdrawn in light of Applicant's amendments to the claims.

Claim 13 is unclear as amended. Applicant has added step (iii) to the claim. It is not clear if the step is intended to indicate that if the oocyte is not in metaphase that the step does not occur at all or if the step is to occur once the oocyte reaches metaphase. The step is also unclear as it refers to activating the reconstituted embryo if said recipient oocyte is in metaphase. However, if the oocyte has been treated to form an embryo, then the oocyte no longer exists. It appears that Applicant may be substitution the term “embryo” for a “nuclear transfer unit”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351 (a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 13-15, 17-19 under 35 U.S.C. 102(e) as being anticipated by Wangh et al. (US Patent 6,753,457 B2) is withdrawn in light of Applicant's Applicant's amendments requiring use of polyanions to induce isomorphic nuclear swelling.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a

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whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 13-15, 17-24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wangh et al. (US Patent 6,753,457 B2) is withdrawn. A new rejection appears below.

Claims 13-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wangh et al. (US Patent 6,753,457 B2) in view of Samocha-Bone et al (1998, Molec. Human Reprod., 4:133-137).

Wangh *et al.* teach methods of reprogramming nuclei for a variety of applications including for use in generating nuclear transfer units to clone whole animals from somatic cell nuclei (see section IX, column 31 for example). More specifically, as directed to the instantly claimed methods, Wangh *et al.* teach optimization steps where donor cell nuclei were isolated and treated with trypsin (claim 15) and lysolecithin (claim 18). With respect to the step (b) for swelling, this was effectively accomplished during the isolation of the nuclei and the presence of detergents in the isolation buffers in the presence of CSF and polyanions (see columns 22-23). Finally, among the various methods known and used to introduce an isolated nucleus, Wangh *et al.* teach the use of microinjection. Wangh *et al.* teach that any animal, in particular mammals, can be generated using the method of nuclear transfer and specifically reduce to practice the use of microinjection. However, Wangh *et al.* fails to teach other methods of cell fusion or specific species of mammals such as cows, pigs and sheep. At the time of filing methods of practicing insertion of the donor cell into the recipient oocyte were performed by various methods and devices conventional to a particular laboratory. Similarly, at the time of filing the specific mammals that were the subject of research and being generated by nuclear transfer were sheep, cows and pigs. The present disclosure indicates that any method for nuclear transfer known in the art can be used and would be adapted to the methods of treating the nuclear donor cell as instantly claimed, therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use

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the methods of Wangh *et al.* generally disclosed for generating ungulates such as cows, pigs and sheep, as well as use the methods established to most effectively generate the NT unit for each of these mammals. One having ordinary skill in the art would have been motivated to substitute for microinjection other methods such as electrofusion because of the success in a particular species of animal, ease over microinjection or availability of equipment in a given laboratory. Similarly, the generation of a particular mammal would be obvious and dependent on an individual's research model. The instant disclosure relies on the methods of nuclear transfer known in the art at the time of filing, so there would have been a reasonable expectation of success given the results of Wangh *et al.* and those generally known in the art for the use of other NT transfer methods and for the production of other mammals. While Wangh teaches that polyanions can be added to increase nuclear swelling (chromatin decondensation), Wangh does not teach use of polyanions without use of CSF.

However, use of polyanions to cause chromatin decondensation to allow for DNA to bind to maternal histones was known at the time of filing. Samocha-Bone taught sperm nuclear swelling and chromatin decondensation using polyanions such as heparin (see page 133, col. 1; page 135, col. 1, last paragraph-col2. paragraph 3). Samocha-Bone taught the substitution of polyanions for factors in oocytes (CSF) to cause in vitro swelling.

It would have been obvious for one of skill in the art at the time of filing to substitute the method of swelling a nucleus using CSF and polyanions as taught by Wangh with the method of swelling a nucleus using polyanions as taught by Samocha-Bone. One would have been motivated to make such a substitution because it was recognized in the art that either method could be used to swell a nucleus. One would have a reasonable expectation of success in replacing the nuclear swelling step of Wang with that of Samocha-Bone as Samocha-Bone taught the effective use of polyanions in nuclear swelling.

Furthermore, simple substitution of one known equivalent element for another to obtain predictable results is obvious. KSR forecloses the argument that a specific teaching, suggestion, or

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motivation is required to support a finding of obviousness. The instant rationale for obviousness is further based in a choosing from a finite number of predictable solutions, rendering it obvious to try, with a reasonable expectation of success. See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (available at <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>).

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Conclusion

No claim is allowed. The instant action is Non-Final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Valarie Bertoglio/
Primary Examiner
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